

STATE OF FLORIDA DEPARTMENT OF HEALTH BOARD OF PHARMACY

In Re: PETITION OF **INFUSION PARTNERS** FOR WAIVER OF RULE 64B16-28.113, F.A.C.

ORDER GRANTING PETITION FOR WAIVER OF RULE 64B16-28.113, F.A.C.

THIS MATTER came before the Board of Pharmacy (hereinafter "the Board"), at a duly noticed public meeting held on October 16, 2007, in Tallahassee, Florida, on the petition of Infusion Partners (hereinafter "Petitioner"), for a waiver of administrative Rule 64B16-28.113, Florida Administrative Code. (A copy of the Petition is attached hereto and incorporated as Exhibit A).

The Petitioner was represented by Diana Figueroa. The Board was represented by Reginald D. Dixon, Assistant Attorney General.

After a complete review of the record in this matter, including consideration of the Petitioner's written evidence, the Board makes the following findings and conclusions:

FINDINGS OF FACT

1. Petitioner is a licensed community pharmacy (PH 14063) located at 6490 West 20th Avenue, Hialeah, Florida 33016.

2. Petitioner filed an application seeking to license a special Parenteral/Enteral Extended Scope pharmacy at the same location as Petitioner's community pharmacy.

3. The Petitioner would have separate inventories for the two pharmacy permits.

4. Petitioner has already expended over \$30,000 in rental and consultant fees, regarding the set up of this new special pharmacy.

5. Petitioner is seeking a waiver of Rule 64B16-28.113, F.A.C., which prohibits

more than one pharmacy permit to be located at a specific location.

6. The purpose for the underlying rule is to protect the health, safety and welfare of patients by ensuring that the appropriate level of supervision of the pharmacy is available.

7. There is competent, substantial evidence to support the Board's findings and conclusions.

CONCLUSIONS OF LAW

1. The Board has jurisdiction over this matter pursuant to 120.542, Florida

Statutes.

2. The purpose of the underlying statutes is to protect the public health, safety,

and welfare.

3. Section 120.54(2), Florida Statutes, provides:

Variances and waivers shall be granted when the person subject to the rule demonstrates that the purpose of the underlying statute will be or has been achieved by other means by the person and when application of a rule would create a substantial hardship or would violate principles of fairness. For purposes of this section, "substantial hardship" means a demonstrated economic, technological, legal, or other type of hardship to the person requesting the variance or waiver. For purposes of this section, "principles of fairness" are violated when the literal application of a rule affects a particular person in a manner significantly different from the way it affects other similarly situated persons who are subject to the rule.

4. The Petitioner has established that the purposes of the underlying rule would

be achieved by a waiver of the rule.

5. Petitioner has also demonstrated that Petitioner would suffer a substantial

hardship if the Petition is denied.

Therefore it is

ORDERED AND ADJUDGED that:

The Petition for waiver of the rule is **GRANTED**.

This order shall become effective upon filing with the Clerk of the Department of Health.

DONE AND ORDERED, this 19 day of Occombin, 2001.

BOARD OF PHARMACY

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Rebecca R. Poston, R. Ph. Executive Director Florida Board of Pharmacy

NOTICE OF RIGHTS

1. Mediation is not available in this matter.

2. You may seek review of this Order, pursuant to Sections 120.569 and 120.57, Florida Statutes, and Rule 28-107.003 by filing a petition (request) with the Executive Director of the Board, within 21 days of your receipt of this Notice.

A. If you dispute any material fact upon which the Board's decision is based, you may request a hearing pursuant to Section 120.57(1), Florida Statutes. To do so, your petition (request) must contain the information required by Rule 28-106.201, Florida Administrative Code, including a statement of the material facts that are in dispute.

B. If you do not dispute any material fact, you may request a hearing pursuant to Section 120.57(2), Florida Statutes. Your petition (request) must include the information required by Rule 28-106.301, Florida Administrative Code.

3. If you request a hearing, you have the right to be represented by an attorney or other qualified representative, to take testimony, to call or cross-examine witnesses, to have subpoena and subpoena duces tecum issued, and to present written evidence or argument.

4. Unless a request for hearing is <u>received</u> on or before the above-stated deadline, or if a request for hearing is made, but the request is subsequently withdrawn, the Board will act in accordance with the provisions of Section 120.57, Florida Statutes, and Rule 28-106-111(4), Florida Administrative Code, the right to hearing shall be waived and this

Notice on Intent to Deny shall become final agency action.

5. In addition, you may:

A. Request that the matter be reconsidered by the Board, and

B. Request to supplement your application with additional information.

6. This Notice shall be placed in and become a part of the Board's official records and shall become effective upon filing with the Clerk of the Department.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by certified mail to: **Infusal Partners**, 6490 West 20th Avenue, Hialeah, Florida 33014; and by interoffice mail to: **Deborah B. Loucks**, Assistant Attorney General, Office of the Attorney General, The Capitol, PL-01, Tallahassee, FL 32399-1050, this day of <u>OCOMOD</u>, 200

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Deputy Agency Clerk



Charlie Crist Governor Ana M. Viamonte Ros, MD, MPH State Surgeon General

DATE:	August 6, 2007
TO:	Board of Pharmacy Members
THRU:	Rebecca R. Poston, R.Ph., C.Ph. Executive Director
FROM:	Dinah Skmich, Regulatory Specialist II
Re:	Wavier to rule 64B16-28,113

Please find attached a request from Denise Figueroa, RN, General Manager, Infusal Partners. Ms. Figueroa has submitted an application with the Board of Pharmacy for a Special P/E Extended Scope permit. She would like an exception to allow the Special P/E Extended Scope to share the same space as the already licensed Community/PE.

64B16-28.113 Permits; Single Entity; Single Location.

A Board of Pharmacy permit shall be issued only to a single entity at a single location. The service provided by the permit shall be consistent with the issued permit. A single location shall be defined as:

(1) A contiguous area under the control of the permit holder. For purposes of this section, a public thoroughfare will be considered to have not broken the area of contiguity; and

(2) An area not more than one-half mile from the central location of the permit.

Specific Authority 465.005, 465.022 FS. Law Implemented 465.003(10)(a), 465.018, 465.019, 465.0193, 465.0196 FS. History-New 1-30-96, Formerly 59X-28.113.





Joint Commission

July 10, 2007

Florida Board of Pharmacy/ Medical Quality Assurance Sarah Helen Lowe, Consultant Pharmacist 4052 Bald Cypress Way, BIN CO4 Tallahassee, Florida, 32399-3254

Dear Ms Lowe,

2.

3.

In response to our conversation on June 22, 2007, regarding Infusal Partners application for a Special Parenteral/Enteral Extended Scope Permit.

The application is for a separate permit for Special P/E Extended Scope

We are requesting the Board of Pharmacy to grant an exception to allow the Special P/E Extended Scope permit to share the following with Infusal Partners current Community/Special P/E permit (PH14063):

1. Facility and location

Computer system and software. Each permit will have it's own account for the separation and tracking of patient records and prescription logs

17 C M 460

Compounding equipment, references etc.

Clean room

In addition the Extended Scope Permit will:

1. Have a separate DEA number and controlled drug logs

2. We are submitting a new signature page for the application changing the pharmacist of record to Suwannee Medina Beach Pharm D as the Pharmacy Manager for the Special P/E Extended Scope permit.

6490 West 20th Avenue • Miami, Florida 33016-2609 • Tel.: (800) 273-5599, Fax (888) 362-5414 • www.infusal.com

Please do not hesitate to call should you need any further clarification for completion of the application process. We appreciate your assistance and guidance in this matter. I can be reached at 305-362-5599 if you have any questions.

Respectfully submitted,

Denise Figueroa RN General Manager/Reg VP Infusal Partners